

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Investigating the Effect of Synbiotic Supplementation on Inflammatory Indices in Children with Sepsis Hospitalized in the Intensive Care Unit in comparison with placebo

#### Protocol summary

##### Study aim

Investigating the effect of synbiotic supplementation on inflammatory indices in children with sepsis hospitalized in the intensive care unit

##### Design

A clinical trial with a control group, parallel-group, triple-blind, randomized, phase 1 study on 54 patients. Sealed envelope site was used for randomization

##### Settings and conduct

Patients aged 1 month to 10 years with sepsis hospitalized or admitted to the pediatric intensive care unit of Akbar Mashhad Hospital. The intervention group will receive Kid Locket synbiotic product with a daily dose of 2 sachets and the control group will receive 2 placebo sachets for 7 days. The concentration of inflammatory factors (ESR, CRP, TNF  $\alpha$ , IL6) on the seventh day and the duration of hospitalization, the mortality rate, the duration of ventilator connection and the need for antibiotic treatment will be compared in the two groups.

##### Participants/Inclusion and exclusion criteria

inclusion criteria : any patient admitted to the pediatric intensive care unit with a diagnosis of sepsis with the possibility of hospitalization for more than 4 days in the PICU, patients in the age group of 1 month to 10 years, parental consent to participate in the project. Conditions of non-entry: immunodeficiency or malignancy, people who are on steroid therapy or immunotherapy, Congenital malformations incompatible with life, previous gastrointestinal surgery in the last month, ulcerative colitis, short bowel syndrome.

##### Intervention groups

The intervention group will receive Kidilact Synbiotic product containing 10 bacterial strains (produced by zisttakhmir Company) with a daily dose of 2 sachets and the control group will receive 2 placebo sachets (produced by zisttakhmir Company) for 7 days.

##### Main outcome variables

Interleukin 6 :C-reactive protein :Erythrocyte sedimentation rate: Tumor necrosis factor

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230523058266N1**

Registration date: **2023-10-30, 1402/08/08**

Registration timing: **prospective**

Last update: **2023-10-30, 1402/08/08**

Update count: **0**

##### Registration date

2023-10-30, 1402/08/08

##### Registrant information

##### Name

Ali Chamani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4333 4400

##### Email address

chamania4012@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-11-22, 1402/09/01

##### Expected recruitment end date

2024-05-21, 1403/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Investigating the Effect of Synbiotic Supplementation on Inflammatory Indices in Children with Sepsis Hospitalized in the Intensive Care Unit in comparison with placebo

**Public title**  
Investigating the Effect of Synbiotics on Inflammatory Indicators

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Any Patient admitted to the Pediatric Intensive Care Unit with a Diagnosis of Sepsis and Possibility of Hospitalization for more than 4 Days in the PICU children aged 1 month to 10 years consent of parent to participation of their children to study  
**Exclusion criteria:**  
Immunodeficiency or Malignancy steroid Therapy or Immunotherapy Congenital Abnormalities Incompatible with life Previous Gastrointestinal Surgery in the last month Ulcerative Colitis Short Bowel Syndrome

**Age**  
From **1 month** old to **10 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**  
Target sample size: **27**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Blocking using blocks of 4 and 6 Using the site sealed envelope Synbiotics or placebos are packaged as a solution that looks, smells, and tastes the same in containers that look the same. The synbiotic or placebo is packaged in opaque packages with a random allocation number on it. Allocation of random number and preparation of packages containing synbiotic or placebo will be done by a person not involved in patient registration, data collection, data entry and analysis

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
Participant blinding: Due to the administration of a placebo with the same shape, taste and smell as the synbiotic supplement, the patient will be blinded to the treatment itself. Data analyzer: due to the use of the site and random block to allocate the intervention or placebo, the data analyzer will be blinded to the intervention.

Researcher, clinical outcome assessor and clinical caregiver: due to the use of the site and random block for allocating intervention or placebo, the data analyzer will be blinded to the intervention.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

1

### Ethics committee

**Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

**Street address**

Azadi square, Mashhad, Khorasan Razavi

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Approval date**

2023-09-19, 1402/06/28

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1402.352

## Health conditions studied

1

### Description of health condition studied

Sepsis

**ICD-10 code**

A41.9

**ICD-10 code description**

Sepsis, unspecified organism

## Primary outcomes

1

### Description

Interleukin-6

**Timepoint**

The beginning of the study (before the start of the intervention) and the 7th day after the start of taking the synbiotic supplement

**Method of measurement**

Interleukin 6 ELISA kit

## Secondary outcomes

## 1

### **Description**

C reactive protein

### **Timepoint**

The beginning of the study (before the start of the intervention), 7 days after the start of taking the synbiotic supplement.

### **Method of measurement**

Measurement of serum levels

## 2

### **Description**

Tumor necrosis factor

### **Timepoint**

The beginning of the study (before the start of the intervention), 7 days after the start of taking the synbiotic supplement.

### **Method of measurement**

Measurement of serum levels

## 3

### **Description**

Erythrocyte sedimentation rate

### **Timepoint**

The beginning of the study (before the start of the intervention), 7 days after the start of taking the synbiotic supplement.

### **Method of measurement**

Measurement of serum levels

## **Intervention groups**

### 1

#### **Description**

Intervention group: Kidilact synbiotic supplement containing 10 strains of bacteria produced by Zisttakhmir company with a dose of 2 sachets daily for 7 days

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Control group: Placebo from Zisttakhmir 2 sachets daily for 7 days

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Akbar Hospital

##### **Full name of responsible person**

Fatemeh Roudi

##### **Street address**

In front of Shahid Kaveh 14, Shahid Kaveh

Blvd, Taleghani town

#### **City**

Mashhad

#### **Province**

Razavi Khorasan

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#### **Email**

ak.pr@mums.ac.ir

#### **Web page address**

<https://akbar.mums.ac.ir/>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice President of Research and Technology, Mashhad University of Medical Sciences

##### **Full name of responsible person**

Majid Ghayor Mobarhan

##### **Street address**

East door of university campus, Azadi square

##### **City**

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##### **Province**

Razavi Khorasan

##### **Postal code**

9138813944

##### **Phone**

+98 51 3841 1538

##### **Email**

vcresraech@mums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Vice President of Research and Technology, Mashhad University of Medical Sciences

#### **Proportion provided by this source**

100

#### **Public or private sector**

Public

#### **Domestic or foreign origin**

Domestic

#### **Category of foreign source of funding**

*empty*

#### **Country of origin**

#### **Type of organization providing the funding**

Academic

## **Person responsible for general inquiries**

#### **Contact**

##### **Name of organization / entity**

Mashhad University of Medical Sciences  
**Full name of responsible person**  
Fatemeh Roudi  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nutrition  
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East door of university campus, Azadi square  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
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**Position**  
Assistant Professor  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Ali Chamani  
**Position**  
Masters student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nutrition

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No. 404 , 16 Shariati St  
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9313863477  
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+98 51 4333 4400  
**Fax**  
**Email**  
chamaniA4012@mums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Not applicable

### Title and more details about the data/document

The data related to the demographic information of the people, the information of the biochemical tests of the people and the information related to the supplement used in the study will be at the disposal of Mashhad University of Medical Sciences as the organization under its supervision and in the comprehensive database of the University of Sciences. Mashhad Medical Center will be located.

### When the data will become available and for how long

The access period starts 6 months after the results are published.

### To whom data/document is available

The information will be available to the researchers and the industry upon the discretion and approval of all project partners.

### Under which criteria data/document could be used

The information will be available to the researchers and the industry upon the discretion and approval of all project partners.

### From where data/document is obtainable

To receive information, the email of the responsible author and the first author will be provided to people in the journal in which the project will be published, and with an explanation of the reason for the need to access the desired study, if approved and at the discretion of the project partners, access to the data , will be given. Corresponding author: Dr. Fatemeh Roudi Email address: RoudiF@mums.ac.ir Phone: 05131891509 First author: Ali Chamani Email address: chamaniA4012@mums.ac.ir

Phone: 09021530646

**What processes are involved for a request to access data/document**

By requesting by e-mail to the responsible author or the

first author and explaining the reason for the need to access the desired study, the data access plan will be given upon approval and discretion of the colleagues.

**Comments**